

34934-PCT-USA (075188.0112)
PATENTREMARKS

This paper is in response to the final Office Action dated January 21, 2005. Applicants respectfully assert that this Reply is fully responsive to each of the objections raised in the outstanding Office Action.

Claims 1-3, 5-8, 10, 12, 14-15 and 17 were pending in the application. Claims 4, 9, 11, 13 16 and 17 have been canceled without prejudice to Applicants' right to pursue the canceled subject matter in other applications. Applicants note with appreciation that the Examiner has withdrawn objections to the specification and to Claim 16 in the light of Applicants' response of October 21, 2004.

Claims 1 and 12 are currently amended to recite "a line of interest that is recalcitrant or unsuited to transformation." The amended claims are fully supported by the originally filed specification at page 2, lines 3-4 and page 3, lines 3-7. Claim 7 which is dependent on Claim 1 is amended to read "wherein the said transgene encodes a protein which" and does not contain new matter.

Applicants request the Examiner to consider new Claim 18 which is limited to maize and, in light of the Examiner's remarks, Applicants believe to be in allowable form. Claim 18 is fully supported by the originally filed specification, and finds support in the originally filed specification at, for example, page 22, line 26, to page 23, line 19. As such, no new matter has been added. As such, claims 1-3, 5-8, 10, 12, 14-15 and 18 will be pending on entry of the amendments herein.

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PATENT**THE CLAIMS ARE ENABLED**

Claims 1-3, 5-6, 8, 10, 12, 15 and 17 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement because the claims allegedly "contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Office Action at pages 2-9. The rejection is repeated for the reasons of record set forth in the June 25, 2004 Office Action, and Applicants' October 25, 2004 arguments are not found to be persuasive.

Applicants respectfully disagree with these rejections, and submit that the pending claims, as amended, are fully enabled by the originally filed specification, drawings and claims. As a preliminary matter, Applicants respectfully request the withdrawal of rejection of the canceled Claim 17.

The instant Office Action appears to state that the presently claimed invention is not enabled because it broadly claims applicability to different plant types while allegedly only disclosing the use of maize plants (Office Action at page 3). Applicants respectfully direct the Examiner's attention to new Claim 18, which is limited to maize and, considering the Examiner's position, is believed to be in allowable form.

The Examiner further alleges that Applicants' arguments relating to the methods for analyzing and comparing genomes as being known in the art is not persuasive (Office Action at page 2-3). The Examiner has not been persuaded to withdraw rejections relating to the "second line of interest" as claimed (Claims 5 and 14) since the specification allegedly only provides evidence for the use of maize (Office Action at pages 4-5). The Examiner alleges that

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use of commercial elite lines is not enabling for any plant since Applicants' argument that maize exemplifies the genus, is not persuasive (Office Action at page 6). The Examiner reiterates cited references Welsh *et al.* (Nucleic Acids Res. (1990) 18(24): 7213-7218; hereinafter "Welsh *et al.*") and Staub *et al.* (HortScience (1996) 31(5):729-741; hereinafter "Staub *et al.*") to demonstrate the alleged unpredictability inherent in applying any marker system to a wide variety of genotypes, thereby requiring undue experimentation to determine a suitable marker system (Office Action at pages 7-8).

Applicants respectfully note that transformation of several plant species has been achieved by utilization of T-DNA vectors. For example, various sunflower genotypes (Gurel *et al.*, Tr. J of Botany, (1999) 23:171-177), various Oilseed rape (*Brassica napus*) cultivars (Damgaard *et al.*, Transgenic Research (1997) 6: 279-288), various tomato cultivars (Davis *et al.*, Plant Cell Tissue and Organ Culture (1991) 24:115-121), canola (Stewart *et al.*, Plant Physiol (1996) 112:115-120) and melon (Bordas *et al.*, Transgenic Research (1997) 6:41-50) have been transformed using *Agrobacterium*-mediated gene transfer methods. Thus all the claimed groups of plants including crop plants, vegetables, and flowers are represented as amenable targets for *Agrobacterium*-mediated gene transfer.

Further, Applicants respectfully note that numerous maize lines can be used for hybrid transformation. Ranch *et al.* (U.S. Patent Application No. 10/784,418 filed February 23, 2004 and published September 30, 2004 under Publication No. US2004/0194161) discloses transforming a hybrid plant which is a cross of Hi-II, A188 or another donor parent with 29 examples of maize lines that are "recalcitrant inbred used in product development that exhibits no or poor transformability" (at paragraph [0024]). Also, contrary to the Examiner's assertion,

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Applicants are unable to find any evidence presented by the Examiner in this or the June, 25, 2004 Office Action in support of the contention that transformability is genotype-dependent (see instant Office Action at page 3, lines 15-16). In addition, enablement is particularly demonstrated in maize exemplified by the A188 line which functions as a line suited for transformations while others have demonstrated the usability of the Hi-II line for hybrid transformation. Applicants, therefore, submit that the claims are enabled for all groups of plants claimed in the instant invention, but nevertheless present for the Examiner's consideration new Claim 18 which is directed to maize.

As regards to the rejection relating to the comparison of genomes, Applicants note that Welsh *et al.* (cited by the Examiner) demonstrates that genomes can be discriminated, and that the described method (which does not necessitate any prior sequence information) can be performed with all genomes, and has been successfully used to distinguish three related varieties of rice. Applicants also note that Examiner has not explained why Welsh *et al.*, does not in fact actually exemplify the level of skill in the relevant art and, indeed, enable the discrimination of related genomes. Applicants believe that these persuasive arguments were provided in their October 21, 2004 response, and reiterate that: a) methods for analyzing and comparing genomes of transformed plants are in an art where the level of skill is already relatively high; and b) the law on enablement allows for some experimentation. *See In re Wands*, 858 F.2d at 737 (Fed. Cir. 1988). Thus, Applicants contend that the instant invention is fully enabled for methods for analyzing and comparing genomes.

The Examiner has rejected claims relating to the "second line of interest" most pertaining to Claims 5 and 14, since the specification allegedly only provides evidence for the

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use of maize. As noted for the rejection of claims related to transformation of several plant species *supra*, we cite here several examples representing plants belonging to flower, crop plant or vegetable plant types that are demonstrably amenable to *Agrobacterium* mediated transformation *i.e.* various sunflower genotypes (Gurel *et al.*, Tr. J of Botany, (1999) 23:171-177), various Oilseed rape (*Brassica napus*) cultivars (Damgaard *et al.*, Transgenic Research (1997) 6: 279-288), various tomato cultivars (Davis *et al.*, Plant Cell Tissue and Organ Culture (1991) 24:115-121), canola (Stewart *et al.*, Plant Physiol (1996) 112:115-120) and melon (Bordas *et al.*, Transgenic Research (1997) 6:41-50). Applicants have in addition amended Claims 1 and 12 to recite "a line of interest that is recalcitrant or unsuited to transformation." Claim 5 is dependent on Claim 1 and Claim 14 depends from Claim 5. Thus the claims are fully enabled for the second line of interest.

Applicants further note that the references cited above provide examples of proteins that confer agronomic properties and/or properties of resistance to disease *e.g.* a protein conferring salt tolerance (Bordas *et al.*, Transgenic Research (1997) 6:41-50) or insect control gene (Stewart *et al.*, Plant Physiol (1996) 112:115-120). Applicants have amended Claim 7 to read: "[t]he method of Claim 1, wherein the said transgene encodes a protein which confers agronomic properties and/or properties of resistance to diseases" which more particularly points out and distinctly claims the claimed subject matter. It is also noted that, from the steps of Claim 1, it is clear that the nature of the transgene is not likely to affect the claimed methods. Thus, the invention is clearly enabled for claims directed to proteins conferring agronomic or disease resistance.

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Applicants also note the Examiner acknowledges that commercial elite lines are well known in the art (Office Action at page 6, lines 12-13). The arguments presented to overcome the rejections of second line of interest and examples of proteins cited above, apply equally to the rejection cited by the Examiner for claims relating to commercial elite lines (*i.e.* Claim 8, which is dependent on Claim 1). Finally, Applicants reiterate that Welsh *et al.*, as well as the highly developed state of the art to which this invention is most related, evidence that the Examiner's rejection, which is based on the number of markers necessary to follow selection and alleged unpredictability of recovering the same, is unsound.

For the reasons cited above, Applicants respectfully request that the rejection of Claims 1-3, 5-8, 10, 12, 14-15 and 18 under 35 U.S.C. §112 first paragraph, for lack of enablement be removed.

THE CLAIMS ARE SUPPORTED BY THE SPECIFICATION

Claims 1-3, 5-6, 8, 10, 12, 15 and 17 are rejected under 35 U.S.C. §112, first paragraph for allegedly failing to comply with the written description requirement. The Examiner alleges that the specification only draws reference from work done by others and does not demonstrate that the inventors had possession of the claimed invention at the time the application was filed (Office Action at pages 8-9). Applicants respectfully disagree. As a preliminary matter Applicants respectfully request the withdrawal of rejection of canceled Claim 17.

Applicants note that the Examiner has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in an Applicant's disclosure a

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description of the invention defined by the claims (541 F.2d at 265, 191 U.S.P.Q. at 98; *Ex parte Sorenson*, 3 U.S.P.Q. 2d 1462, 1463 (Bd. Pat. App. & Inter. 1987)). Applicants contend that this burden has not been met in either the June 25, 2004 Office Action or in the present Office Action. Applicants further contend that the steps of the methods are well enunciated in the claims and in the specification. Further it has been demonstrated, using multiple references (including references cited by the Examiner, at page 18 of the Response filed October 21, 2004), that all the individual steps of the invention are well-known in the art including documents already of record demonstrating the existence of broad knowledge of these methods in the existing art at the time of filing of the invention. The claimed method is a particular combination of the known methods. Therefore a person skilled in the relevant art would readily understand that the inventors had this combination in their possession at the time of filing the application. For these reasons, Applicants respectfully request that the rejection of Claims 1-3, 5-8, 10, 12, 14-15 and 18 under 35 U.S.C. §112 first paragraph, under the written description requirement be removed.

THE CLAIMS ARE NOT ANTICIPATED BY RAGOT

Claims 12 and 17 are rejected under 35 U.S.C. §102(b) as being anticipated by Ragot *et al.* (*Techniques et utilisations des marquers moleculaires*; Montpellier (France) 29-31 mars 1994; Ed. INRA, Paris 1995 (*Les Colloques*, n72); pages 45-56; hereinafter “Ragot *et al.*”). The Examiner alleges that Ragot *et al.*’s method could theoretically produce an isotransgenic line only containing genomic sequences from the line of interest and is therefore indistinguishable from the claimed invention (Office Action at pages 9-10). Applicants respectfully disagree, at

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least because theoretical assumptions cannot ground a rejection based on anticipation. As a preliminary matter Applicants respectfully request the withdrawal of rejection of the canceled Claim 17.

Nevertheless, Claim 12 is amended herein to read "An isotransgenic line as compared to a line of interest that is recalcitrant or unsuited to transformation, wherein said isotransgenic line only differs from said line of interest by the presence of the T-DNA containing the transgene." Ragot *et al.* do not specify use of a line that is recalcitrant or unsuited to transformation. Amended Claim 12 is, therefore, not anticipated by Ragot *et al.* In addition, Applicants reiterate that Ragot *et al.* clearly produce "near isogenic lines" whereas the linkage drag around the transgene would be perfectly null in the claimed invention, since the "said isotransgenic line only differs from said line of interest by the presence of the T -DNA containing the transgene" (Claim 12). As such, the pending claims are clearly distinct from the lines disclosed by Ragot *et al.* Applicants, therefore, respectfully request withdrawal of the rejection of Claim 12 under U.S.C. §102(b).

THE CLAIMS ARE NOT OBVIOUS IN VIEW OF THE CITED ART

Claims 1-3, 5-8, 10, 12, 14-15 and 17 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ishida *et al.*, (Nature Biotech. (1996) 14:745-750; hereinafter "Ishida *et al.*") in view of Does *et al.*, (Plant Mol. Biol. (1991) 17:151-153; "hereinafter "Does *et al.*""), Hiei *et al.*, (Plant Journal (1994) 6(2):271-282; hereinafter "Hiei *et al.*"'), Armstrong *et al.*, (Theoretical and Applied Genetics (1992) 84:755-762; hereinafter "Armstrong *et al.*"') and Ragot *et al.* as stated for claims 1-12 and 14-16 on pages 15-18 of the previous Office Action (Office

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Action at pages 10-12). Applicants respectfully disagree. As a preliminary matter, Applicants respectfully request the withdrawal of rejection of the canceled Claim 17.

To establish a *prima facie* obviousness, all the claim limitations must be taught or suggested by the prior art (*In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494,496 (C.C.P.A. 1970) states that "All words in a claim must be considered in judging the patentability of that claim against the prior art." The Examiner contends that the rejection of claims is based on combinations of references while Applicants' have erroneously considered each reference individually in their October 21, 2004 response at page 23. Applicants maintain that the selection step in Claim 1 is absent and not suggested by the prior art, as discussed in Applicants' October 21, 2004 response. Applicants assert that each cited document was not merely addressed individually, but was also addressed in the proposed combination (October 21, 2004 response at page 23).

The Examiner further contends that Applicants' statements: (1) "the claimed methods for producing isotransgenic lines require transforming a suitable line, selecting appropriate transformants, and performing backcrosses with a line of interest" (October 21, 2004 response at page 17, lines 4-6); (2) that "the present invention is directed to obtaining isotransgenic lines by combining multiple steps . . . each step being known in the art" (October 21, 2004 response at page 17, lines 18-21); and (3) "the nature of the claimed invention is a combination of known methods" (October 21, 2004 response at page 18, lines 6), render the claims obvious per Applicants' admissions. Applicants' have made no such admission and assert that the Examiner has improperly used Applicants' teachings as a blueprint to reconstruct the

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claimed invention bit-by-bit from disparate references the contain no motivation to combine their disclosures.

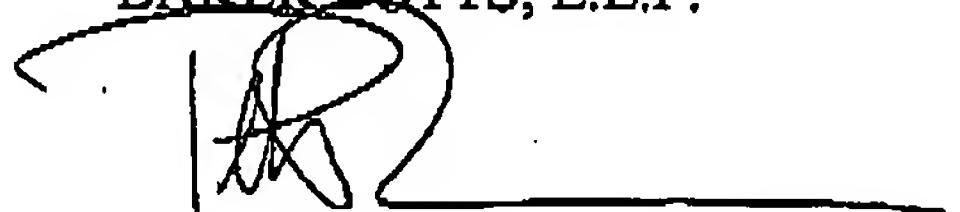
As such, Applicants respectfully request that the rejections under 35 U.S.C. §103(a) in view of the combination of Ishida *et al.*, Hiei *et al.*, Does *et al.*, Armstrong *et al.*, and Ragot *et al.*, be withdrawn.

CONCLUSION

Applicants believe that in light of the foregoing amendments and remarks, the claims are in condition for allowance, and accordingly, respectfully request withdrawal of the outstanding objections and rejections. The Examiner is kindly invited to contact the undersigned if helpful to advance the application to allowance, which is earnestly sought.

Respectfully submitted,

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